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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,448	09/29/2005	Jacek Rozga	61772USN(51321)	6295
21874 7590 12/11/2007 EDWARDS ANGELL PALMER & DODGE LLP P.O. BOX 55874 BOSTON, MA 02205			EXAMINER DEAK, LESLIE R	
			ART UNIT 3761	PAPER NUMBER
			MAIL DATE 12/11/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/524,448

Applicant(s)

ROZGA, JACEK

Examiner

Leslie R. Deak

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 February 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3/24/06, 4/30/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 10 and 13-17 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,191,182 to Popovich et al.

In the specification and figures, Popovich discloses the apparatus as claimed by applicant. With regard to claim 10, Popovich discloses a first catheter attached to fluid line or tubing 1 to attach the treatment apparatus to the patient and withdraw blood from the patient, a second catheter attached to fluid line 13 or tubing that attaches the treatment apparatus to the patient and returns treated fluid to the patient (see column 6, lines 10-58). The apparatus further comprises a pump 3 for propelling the patient's blood through tubing line 1, second tubing 13 for conveying filtered blood back to the second catheter, plasma filter 9 comprising a housing, with inner 9a and outer 9b compartments, semipermeable membrane, blood inlet, blood outlet, and filtrates outlet (see FIG 2). The apparatus further comprises a third tubing 23/35, connected to a pump 37 that assists in regulating transmembrane fluid flow.

With regard to applicant's claimed "retention coefficient" of undefined blood components within the range of 0.5-1.0, Popovich discloses the clearance of selected

molecules in the claimed apparatus within the claimed range (see Table II), indicating that the semipermeable membrane within filter 9 meets the limitations of the claims.

With regard to applicant's claimed filtration rate and treatment time, such limitations are considered by the Examiner to be statements of the intended use of the claimed device. It has been held that a recitation with respect to the manner in which a claimed apparatus is claimed to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. In the instant case, applicant has not set forth any structural differences that perform the claimed function, and the structure of the claimed device does is not patentably distinguishable from the Popovich reference.

With regard to claim 11, Popovich discloses that the apparatus may combine the catheter means into a single double-lumen catheter (see column 3, lines 63-64).

With regard to claims 13-17, Popovich discloses that it is known in the art to use plasmapheresis processes to filter out particles as small as 10kDa, meeting the limitations of the claims (see column 2, lines 1-5).). It has been held that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See MPEP 2144.05(II)(A). It is the position of the examiner that since Popovich teaches that such processes are well-known in the art, routine experimentation would have arrived at the invention claimed by applicant.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,191,182 to Popovich et al in view of US 4,350,156 to Malchesky et al

With regard to claim 1, Popovich discloses a method of removing plasma fractions comprising the steps of attaching a treatment system to the patient comprising a filter 9, removing blood from the patient via line 1 and conveying it to the filter 9, filtering the blood to remove certain fractions from the blood, mixing the filtered fluid with a replacement fluid, and returning it to the patient (see column 6, lines 10-58).

Popovich is silent as to the filtration rate and time of treatment. However, Malchesky discloses a method and apparatus for plasmapheresis wherein treatment runs from 2-4 hours at a rate of 12.5-25 mL/min in order to provide efficient treatment (see column 7, lines 40-45). It has been held that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See MPEP 2144.05(II)(A). It is the position of the examiner that since Popovich discloses the claimed method, and Malchesky discloses the claimed flow rate, the references taken together suggest the claimed method, which was known in the prior art.

With regard to claims 2-6, Popovich discloses that it is known in the art to use plasmapheresis processes to filter out particles as small as 10kDa, meeting the limitations of the claims (see column 2, lines 1-5).). It has been held that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See MPEP 2144.05(II)(A). It is the position of the examiner that since Popovich teaches that such processes are well-known in the art, routine experimentation would have arrived at the invention claimed by applicant.

With regard to claims 7-8, Malchesky discloses a method and apparatus for plasmapheresis wherein treatment runs from 2-4 hours at a rate of 12.5-25 mL/min in order to provide efficient treatment (see column 7, lines 40-45). It is the position of the Examiner that Malchesky's disclosed 12.5mL/min filtration rate corresponds to applicant's claimed flow rate of "about" 1-10mL/min, meeting the limitations of the claims.

With regard to claim 9, Popovich discloses that the replacement fluid may comprise clean plasma or serum albumin, meeting the limitations of the claim (see column 3, lines 55-60).

5. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,191,182 to Popovich et al in view of US 2001/0051106 to Matson et al. In the specification and figures, Popovich discloses the apparatus substantially as claimed by applicant (see rejection above) with the exception of a plasma sorption device that is

capable of receiving and adsorbing filtered plasma. Matson discloses a hemofiltration system that passes blood from a patient into a hemofilter 102 that filters out molecules greater than a selected molecular weight (see FIG 1, paragraph 0050). The ultrafiltrate 111 leaves the hemofilter and proceeds to adsorptive device 108 that removes a target molecule from the ultrafiltrate (see paragraph 0054 and delivers it to a receptacle or tubing 115/123. The adsorber removes toxins that pass through the filter membrane to treat various combinations of patient illness (see paragraph 0054). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to add a sorption means as disclosed by Matson to the plasmapheresis apparatus disclosed by Popovich in order to remove toxins that pass through the filter membrane, as taught by Matson.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- a. US 3,579,441 Brown
 - i. Blood purification by dual filtration
- b. US 4,648,974 Roskopf et al
 - ii. Filter for extracorporeal constituent separation


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on Monday - Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Leslie R. Deak
Patent Examiner
Art Unit 3761
6 December 2007